

REMARKS/ARGUMENTS

Claims 1-40 are pending in this application. Claim 6 is objected to. New claims 41-45 have been added. Support is found in the application as filed.

In response to the Office communication dated May 18, 2004, the Examiner states "the amendment to the claims filed on 3-01-04 does not comply with the requirements of 37 CFR 1.121(c) because Applicants have made multiple changes to the claims that are not indicated by bracketing, underlining, or strike-through." *PTO Paper* dated May 18, 2004 at page 2.

Applicants have amended the claims so that they comply with 37 CFR 1.121(c).

Additionally, the Examiner state there is no support for the range -204-190 in claim 8 or in the specification as filed.

Applicants have amended claim 8 so that it now more clearly reads the nucleotides at position -214 through -190.

In response to the Office communication dated November 28, 2003, Applicants submit a Preliminary Amendment and a §1.131 Declaration was filed on August 14, 2002 with the Patent and Trademark Office; however it was never received by the Examiner.

Pursuant a telephonic discussion between the Examiner and the undersigned Attorney, Applicants submitted as evidence a copy of the Preliminary Amendment (Exhibit AA), a copy of the Transmittal (Exhibit BB), a copy of the Auto-Reply Facsimile Transmission (Exhibit CC), and a copy of the Declaration of Joseph Jilka (Exhibit DD) along with the previously submitted Exhibits (Exhibits A-G). Because of the failure of the Examiner to receive this Preliminary Amendment and Declaration, the Office Action of November 28, 2003 did not take into consideration previous amendments and remarks/arguments made by Applicants.

Applicants have herein incorporated the changes that were in the Preliminary Amendment submitted back in August of 2002, as well as changes made to overcome rejections in the Office Action dated November 28, 2003. Pursuant a telephonic discussion with the Examiner on June 8, 2004, the Examiner indicated that this would clarify matters. The Examiner indicated it would not be necessary to send in another copy of the exhibits. However, if the Preliminary Amendment, Declaration and Exhibits that were previously submitted have not been entered into the record, Applicants respectfully request that they are entered into the record of the above-identified application.

The following Remarks are in response to the Office communication dated November 28, 2003.

I. PRIORITY

The Examiner states "Applicants have not included an amendment to the first line of the specification, which indicates that the instant application is a continuation of U.S. Serial No. 09/590,558, filed June 9, 2000, now abandoned." *PTO Paper* dated November 28, 2003 at page 2.

Applicants have herein amended the specification to include a reference to the prior non-provisional application. Applicants respectfully submit that the priority reference was noted in the Application Data Sheet when the application was submitted.

II. CLAIMS OBJECTIONS

A. *Claims 3-4, 6, 11, 21-22, 26, and 30*

Claims 3-4, 6, 11, 21-22, 26, and 30 were objected to for failing to recite appropriate sequence identifiers. *PTO Paper* dated November 28, 2003 at page 2.

Applicants cancelled claims 2-7 and 20-26 in the Preliminary Amendment making this objection moot. Also, claims 11 and 30 were previously amended in the Preliminary amendment to recite a sequence identifier, thus making this rejection moot.

III. CLAIM REJECTIONS – 35 U.S.C. §112

A. *Claims 4, 7-9, 10-12, and 20-31*

Claims 4, 7-9, 10-12, and 20-31 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner states “claim 4 recites the limitation ‘said heat shock sequence’ in claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 7 recites the limitation ‘the heat shock element region’ in claim 1. There is insufficient antecedent basis for this limitation in the claim.” *Id.* at page 3.

Claims 4 and 7 were cancelled in the previously submitted Preliminary Amendment, thus making this rejection moot.

Next, the Examiner states “claims 8 and 27 recite the limitation ‘the overlapping HSE’. There is insufficient antecedent basis for this limitation in these claims. Additionally, claims 8 and 27 recite ‘wherein said sequence includes a deletion of the overlapping HSE at position - 204 - -190.’ This statement is vague and indefinite since Applicants did not indicate which specific nucleic acid sequence the position - 204 - -190 refers to.” *Id.*

Claims 8 and 27 were previously amended in the Preliminary Amendment to recite proper antecedent basis and to indicate which specific nucleic acid sequence the position, as amended -214 - -190 refer to, thus making this rejection moot. Applicants respectfully submit support for this range is found in the application as filed.

Further, the Examiner states “claim 9 recites ‘the promoter sequence of claim 1 further comprising a DNA binding factor or transcription factor’. This phrase is vague and indefinite

since DNA binding factors and transcription factors are known in the art to be proteins that bind to specific sequences within a nucleic acid molecule, they are not known to be nucleic acid sequences. Therefore, it is unclear how the nucleic acid promoter of claim 1 is to comprise a DNA binding factor or a transcription factor." *Id.*

Claim 9 has been amended herein to recite that the promoter sequence contains a "transcription factor-binding site" since it is known in the art that promoter sequences may contain a site within the sequence for the binding of a transcription binding factor or a DNA binding factor, thus alleviating this rejection.

The Examiner states "claims 10-12 recite the limitation 'wherein said transcription factor' in claim 1. There is insufficient antecedent basis for this limitation in the claim." *Id.* at page 4.

Claim 10 was previously amended in the Preliminary Amendment to provide proper antecedent basis by changing its dependency to claim 9, thus making this rejection moot. Claims 11-12, by virtue of their dependency to other claims have proper antecedent basis, thus making this rejection moot.

The Examiner states "claims 11-12 recites 'said Psi element' in claim 10. There is insufficient antecedent basis for this limitation in the claim." *Id.*

Applicants respectfully submit claims 11-12 were previously amended in the Preliminary Amendment. Claim 11 was amended to recite "a Psi element", thereby providing proper antecedent basis, thus making this rejection moot. Claim 12 was amended to recite "said Psi element", thereby providing proper antecedent basis, thus making this rejection moot.

Further, the Examiner states "claims 20-31 recite '[t]he promoter sequence of claim 19,' this phrase is unclear because claim 19 recites '[A] method for causing expression of a structural gene.' It appears that dependent claims 20-31 are drawn to product claims and not to a method,

as recited in independent claim 19. It is likely that Applicants intended claim 20, for example, to recite: '[T]he method of claim 19, wherein the promoter sequence includes a single heat shock element". *Id.*

Claims 20-26 were cancelled in the Preliminary Amendment, thereby making this rejection moot. Claims 27-31 have been amended to be drawn to method claims, thus alleviating this rejection.

The Examiner states "claims 23-26 recite the limitation 'said sequence comprises two adjacent heat shock elements,' in claim 20. There is insufficient antecedent basis for this limitation in claim 20, since claim 20 recites that the sequence includes a single heat shock element." *Id.*

Claims 23-26 were cancelled in the Preliminary Amendment, thereby making this rejection moot.

IV. CLAIM REJECTIONS-35 U.S.C. §102

A. *Claims 1-5, 13-22, 32-35, and 39*

Claims 1-5, 13-22, 32-35, and 39 were rejected under 35 U.S.C. §102(b) as being anticipated by Quail et al. (EP 034292682) or under 35 U.S.C. §102(e) as being anticipated by Quail et al. (U.S. Patent 6,054,574). The Examiner states Quail teaches each and every aspect of the instant invention thereby anticipating Applicants' claimed invention.

Claims 2-5, 22 and 39 were cancelled in the Preliminary Amendment, thus making this rejection moot. Independent claim 1 was amended in the Preliminary Amendment to recite "a ubiquitin promoter sequence, wherein said sequence includes a modification so that there are no heat shock elements." Independent claim 19 was also similarly amended in the Preliminary Amendment to recite "an expression construct comprising a ubiquitin promoter sequence, said

sequence having been engineered so that it comprises no heat shock elements". Therefore, this rejection stands moot. Therefore, the claims read on a promoter sequence having no heat shock elements. Dependent claims 13-18 and 32-35, contain by virtue of their dependency, all the limitations of such patentable independent claims from which they depend.

By contrast, EP 0342926 to Quail discloses in part a ubiquitin promoter region that comprises heat shock consensus elements (see column 14, lines 31-33; column 18, lines 52-54; column 22, lines 37-43; column 23, lines 56-28; and column 24, lines 6-11). Therefore, Applicants claims are patentably distinguishable from EP 034292682 to Quail.

U.S. Patent No. 6,054,574 to Quail does not anticipate under 35 U.S.C. §102(e). Applicants' independent claim 1 was amended in the Preliminary Amendment to recite "a ubiquitin promoter sequence, wherein said sequence includes a modification so that there are no heat shock elements" and independent claim 19 was also amended in the Preliminary Amendment to recite "an expression construct comprising a ubiquitin promoter sequence, said sequence having been engineered so that it comprises no heat shock elements". Therefore, this rejection stands moot.

By contrast, U.S. Patent No. 6,054,574 discloses a plant ubiquitin promoter that has two overlapping heat shock consensus elements (see column 6, line 53; column 11, lines 13-15; column 12, lines 41-44; column 16, lines 20-21; and column 29, lines 41-42). The dependent claims contain by virtue of their dependency, all the limitations of such patentable independent claims from which they depend. Therefore, these claims are felt to distinguish patentably from U.S. Patent No. 6,054,574 to Quail.

Claims 1, 7-8, 13-19, 27, 32-38 and 40 were rejected under 35 U.S.C. §102(a) as being anticipated by Goldsbrough et al. (WO 00/15810).

Applicants respectfully traverse this rejection. Applicants are herein resubmitting the Declaration of Joseph Jilka, which establishes conception and reduction to practice of the invention in the United States prior to the International Publication date of the cited application. Applicants respectfully request the Examiner to withdraw this rejection under §102(a) in light the Declaration and Exhibits submitted herein.

V. CONCLUSION

The Examiner states "claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims." *Id.* at page 7.

Applicants have rewritten claim 6 in an independent form to include the limitations of the base claim and any intervening claims. (See New claim 44). Applicants respectfully request reconsideration.

The Examiner states "claim 26 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office Action and to include all the limitations of the base claim and any intervening claims." *Id.*

Applicants have rewritten claim 26 in an independent form to include the limitations of the base claim and any intervening claims and to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office Action. (See New claim 45). Applicants respectfully request reconsideration.

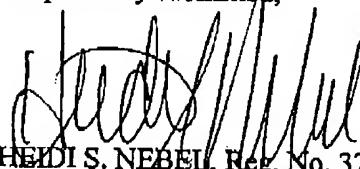
A check in the amount of \$147.00 was previously submitted with the amendment filed March 1, 2004 to cover the cost of the new claims.

This is a request under the provision of 37 CFR § 1.136(a) to extend the period for filing a response in the above-identified application for one month from June 18, 2004 to July 18,

2004. Applicant is a small entity; therefore, please charge Deposit Account number 26-0084 in the amount of \$55.00 for one month to cover the cost of the extension. Any deficiency or overpayment should be charged or credited to Deposit Account 26-0084. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



HEIDI S. NEBEL, Reg. No. 37,719
McKEE, VOORHEES & SEASE, P.L.C.
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309-2721
Phone No: (515) 288-3667
Fax No: (515) 288-1338
CUSTOMER NO: 22885

Attorneys of Record

- pw -